Research Article

Management of stress urinary incontinence in spinal cord injured female patients with a mid-urethral tape – a single center experience

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Context/Objective: Stress urinary incontinence (SUI) affects the quality of life of females with spinal cord injury (SCI), has a negative impact on functional independence and disturbs their psychosocial interaction. Our aim was to assess the efficacy of mid-urethral tapes (MUT) in managing stress urinary incontinence in this population.
Design: Retrospective cohort study.
Participants: SCI females with upper motor neuron lesion and urodynamically proven stress or mixed urinary incontinence that was treated with a mid-urethral tape and followed up for at least 12 months.
Interventions: Mid-urethral tapes such TVT, TOT and mini-Arc. Patient reported outcomes based on the daily use of pads and ICIQ modular questionnaire scores.
Outcome measures: The primary endpoint was defined as the success rate of MUT surgery in managing stress incontinence at 12. The secondary endpoints included the improvement rate at 12 months, the complication rates and the need for additional treatments.
Results: 38 females were studied. At 12 months the overall patient reported success rate was 52.6%. 16% reported significant improvement. 68.4% felt the quality of life to improve. Nine patients develop tape related complications (five de novo urgency, one vaginal extrusion, one frequent dysreflexia and one worsening of incontinence).
Conclusion: Mid-urethral tapes are effective in the management of stress urinary incontinence in female patients with spinal cord injury. There are demonstrable improvements in both continence and quality of life.

Keywords: Stress urinary incontinence, Mid-urethral tapes, Neurogenic bladder, Spinal cord injury

Introduction

Stress urinary incontinence (SUI) is defined by the International Continence Society (ICS) as "involuntary leakage of urine on exertion, effort, coughing or sneezing".[1] It is the most common subtype of incontinence in females with a prevalence that ranges from 8.9% to 45%.[2,3] Whilst it is not considered to be a life threatening condition it seriously impairs the physical, psychological and social well-being of the affected individual and decreases their quality of life.[4] The true incidence of SUI in the female spinal cord injury (SCI) population is unknown. There are data suggesting incontinence in the SCI population is associated with decreased quality of life and negative impact on functional independence and psychosocial interaction.[5,6] Urine leak in SCI individuals also disposes the patients to dermatitis, the need to change clothes, and an increased number of transfers from wheelchair to bed which may provoked further leak episodes.

Spinal injured females may have complex bladder problems; the neurological insult will have conferred upon them a significant bladder abuse. However pre-injury factors should also be taken into account. Many of them will have been parous, be post-menopausal and may have suffered from some degree of incontinence prior to their injury. In addition, SUI may be the

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result of patulous urethra after prolonged urethral catheterization. The World Health Organization describes two age peaks in the incidence of SCI in females; adolescence (15–19) and older age (60+).[7] Individuals with SCI and SUI apart from sphincteric weakness, have the additional issue of a neurogenic bladder.[8] Detrusor muscle function is usually related to the level of the spinal insult and may be overactive, normoactive or underactive.[9] Detrusor overactivity is the most common urodynamic finding in upper motor neuron lesions. In many affected individuals bladder compliance is also impaired, this will have an adverse effect on functional bladder capacity which may have a further deleterious effect upon lower urinary tract function. In order to assess the urinary tract in these individuals video-urodynamic investigation is required.[10–12]

Managing stress urinary incontinence in females with spinal cord injury is challenging. It requires careful assessment and experience in managing spinal injured patients. The main aims of any urological intervention should be to; preserve renal function, prevent infection and provide an acceptable degree of continence. The objective of this study is to assess the efficacy of mid-urethral tapes either as primary treatment or as a part of combination therapy in the management of urodynamically proven SUI in SCI female patients with upper motor neuron lesions.

Methods

Patients

We conducted a retrospective review of all spinal cord injured female patients with either pure stress or mixed urinary incontinence who were treated with a mid-urethral tape. The outcomes of these patients were recorded in a prospective database over a 10-year period. The inclusion criteria were: age greater than 18 years, upper motor neuron lesion confirmed on imaging, baseline video-urodynamics assessment, demonstrating stress incontinence. All patients had to be more than 12 months after their continence surgery. All females with clinical stress urinary incontinence that was not proven urodynamically and cauda equina lesions were excluded from the study.

Protocol

Our current unit protocol is that all new patients undergo a baseline videourodynamic examination approximately three months after their SCI. This investigation is repeated as and when there is a clinical indication such as; change in bladder behavior, complicated urinary tract infections, new hydronephrosis and treatment failures. In addition to this they will all have an annual ultrasound scan of the urinary tract.

Videourodynamic assessments are performed according to the recommendations of the ICS.[13] Video-urodynamic assessments are carried out in supine position using standard urodynamic catheters (6Fr dual bladder catheter and 8Fr slit balloon rectal line) and the filling rate is set at 20ml/min. Voiding phase recording may not be possible due to difficulties in changing position in many of the female patients. The "stop test" is undertaken only in those with an incomplete injury who are able to stand or sit on the commode. Provocation of potential detrusor overactivity is a routine part of the VUDS assessment as it is the measurement of abdominal and detrusor leak point pressures. Coughing, bending forwards and suprapubic tapping are standard provocation maneuvers during filling phase. After assessment all cases are discussed in a dedicated bladder/spinal multidisciplinary team meeting (MDT).

Surgery to insert the mid-urethral tape was carried out under general anesthesia. We used TVT (Tension-free Vaginal Tape) (GYNECARE TVT™ Retropubic System Tension-Free), TOT (Transobturator Tape) (Monarch™) and single incision MiniArc (MiniArc®) based on surgeons preference.

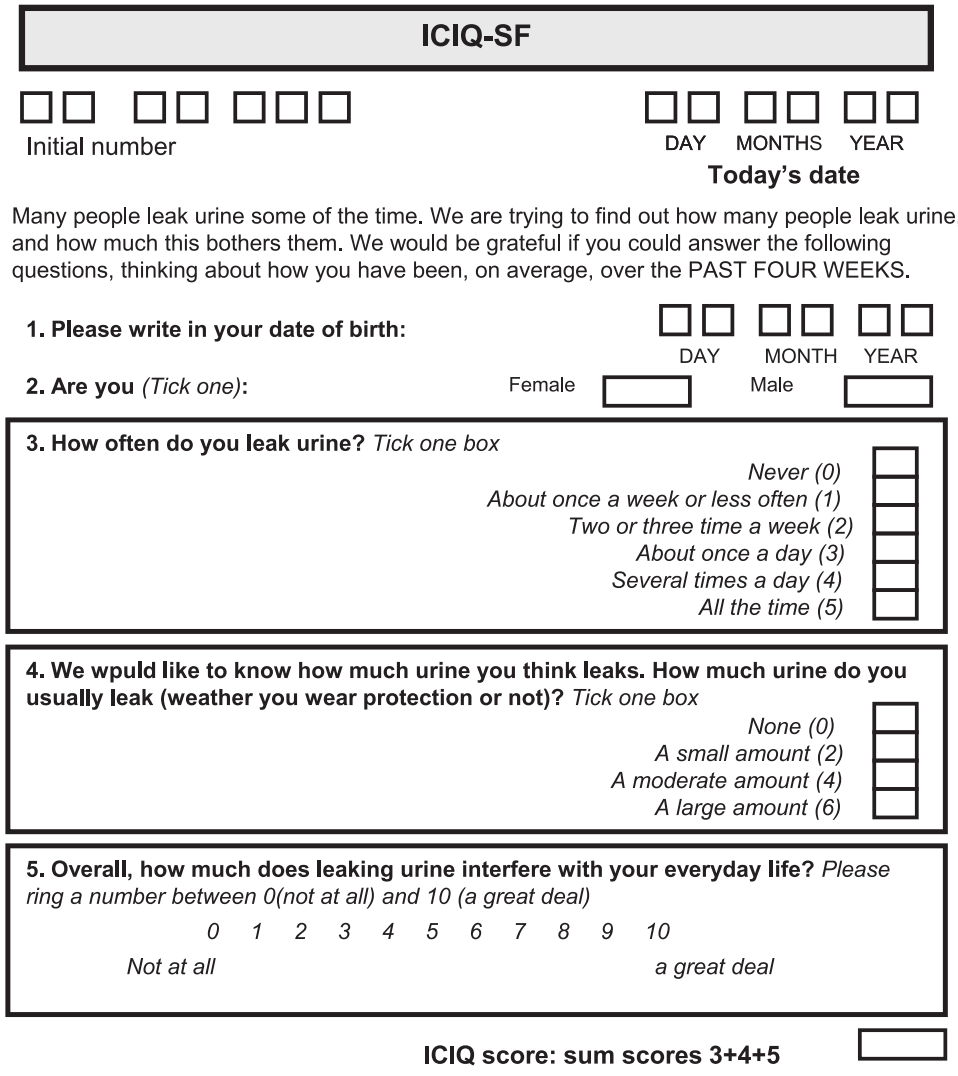
The steps of each procedure are described in detail elsewhere.[14–16] Any additional urological procedures undertaken were also recorded.

Analysis

The primary end point was defined as the success rate of mid-urethral tapes in managing stress incontinence at 12 months; Secondary outcomes included the improvement rate at 12 months, postoperative complications and need for subsequent surgical or medical treatment for incontinence. The outcome was quantitatively defined by the daily use of pads. A cured case would use none or a single safety pad per 24 hours. An improved case would use fewer pads per 24 hours than used to preoperatively.

Data was retrieved from patient records and any additional information required was verified during a telephone consultation for the purposes of this study. Operation notes, clinical follow-ups and all urodynamic traces were reviewed. Postoperative VUDS were not available for all patients, usually in those who had reported a successful outcome.

The International Consultation on Incontinence Modular Questionnaire (ICIQ) was used to objectively assess the response to treatment. The total questionnaire score is the result of answers to questions 3,


ICIQ-SF

☐☐ ☐☐ ☐☐☐
Initial number

☐☐ ☐☐ ☐☐
DAY MONTHS YEAR
Today's date

Many people leak urine some of the time. We are trying to find out how many people leak urine, and how much this bothers them. We would be grateful if you could answer the following questions, thinking about how you have been, on average, over the PAST FOUR WEEKS.

1. Please write in your date of birth: ☐☐ ☐☐ ☐☐ DAY MONTH YEAR

2. Are you *(Tick one)*: Female ☐ Male ☐

3. How often do you leak urine? *Tick one box*
- *Never (0)* ☐
- *About once a week or less often (1)* ☐
- *Two or three time a week (2)* ☐
- *About once a day (3)* ☐
- *Several times a day (4)* ☐
- *All the time (5)* ☐

4. We wpuld like to know how much urine you think leaks. How much urine do you usually leak (weather you wear protection or not)? *Tick one box*
- *None (0)* ☐
- *A small amount (2)* ☐
- *A moderate amount (4)* ☐
- *A large amount (6)* ☐

5. Overall, how much does leaking urine interfere with your everyday life? *Please ring a number between 0(not at all) and 10 (a great deal)*

0 1 2 3 4 5 6 7 8 9 10

Not at all *a great deal*

ICIQ score: sum scores 3+4+5 ☐

Thank you very much for answering these questions

Figure 1 The ICIQ Modular Questionnaire.

4, 5. (Fig. 1). Question 6, "When does urine leak?" was not assessed, as it was not deemed relevant to the spinal cord injury population. Two additional questions were asked which pertained to quality of life:

Has your quality of life been improved following this/these procedure/s?

Improved /same/ worse

Would you recommend this procedure to a friend with similar problem?

Yes / no

For statistical analysis, the statistic software SPSS (IBM Corp. Released 2012. IBM SPSS Statistics for Windows, Version 21.0. Armonk, NY: IBM Corp.) was used. Inferential statistics used for demographic characteristics and baseline calculations. The t-test was used to assess variability. The local ethics committee approved the study and patients gave their verbal consent for data publication.

Results

From 2005 to 2015, a total of 45 SCI female patients were diagnosed with pure stress or mixed urine incontinence and their management included a mid-urethral tape insertion. Of these, 41 fulfilled the inclusion criteria but only 38 were included due to missing data. The demographic characteristics and the SCI details are depicted in Table 1. Nine patients reported a degree of stress incontinence prior to their injury. None had

previously sought urological input for this, as it was not affecting their quality of life.

The most common recorded continence issues and main reasons patients requested urological referral were; leaking during transfers (81.6%), contact dermatitis (65.8%), leaking on coughing and sneezing (39.5%), need for frequent clothes changes (26.3%), offensive smell (23.7%) and leaking between catheterisations (15.8%). One young patient with an L1 incomplete injury complained of impaired sexual life due to urine leakage. It is not clear how many others had impaired sexual function as a result of their bladder problems as this is not currently routinely asked. Furthermore one female with a T4 complete injury was confined to bed as she wished to avoid any transfers due to her profound incontinence.

Preoperative cystoscopy was performed and reported as normal in 26 patients in terms of bladder capacity, bladder mucosa appearance and urethral patency. Three patients were reported as having a patulous urethra, five patients had small capacity, trabeculated bladders and seven patients had bladder debris and bladder stones. Pre-operative videourodynamic parameters are shown on Table 2. 35 patients were diagnosed with intrinsic sphincter deficiency and 3 with urethral hypermobility due to impaired distal mechanism. The median cystometric volume where SUI was evident was 130mls. 32 patients had normo-compliant bladders while six had poor compliance.

In total 21 patients underwent a retropubic TVT, 12 underwent an obturator sling Monarc and 5 had single incision MiniArc. 21/38 (55.3%) patients had an additional procedure undertaken (Table 3).17 patients had concomitant intradetrusor Botulinum toxin injections due to pre-existing detrusor overactivity refractory to oral anticholinergics while, two patients had macroplastique injection for vesicoureteric relfux.

At 12 month follow up, the overall patient reported success rate was 52.6% since 20/38 patients were cured. A further 6/38 (16%) patients reported that their incontinence was much improved and they minimize the use of daily pads. In 12/38 (31%) patients there was no demonstrable improvement in their overall continence (Table 4). The mean overall score of the ICIQ as well as each separate question were significantly improved postoperatively ($P<0.01$) (Fig. 2).

In terms of Quality of life (QoL) 68.4% felt that they had an improvement in their QoL, 21% reported no

Table 1 Baseline characteristics.

Age*, mean, years (SD)	55.8, (14.3)
Range	18–87
Period from injury since tape, mean, months (SD)	76.1,(81.2)
Range	3–301
Follow up, mean, months (SD)	46.7, (31.3)
Range	12–120
Pregnancies/Deliveries	
Nuliparous	11 (28.9%)
1 delivery	22 (57.9%)
≥2 deliveries	5 (13.2%)
Injury details	
Tetraplegics, (%)	8,(21.1%)
Paraplegics, (%)	30, (78.9%)
Complete (ASIA A), (%)	13, (34.2%)
Incomplete	25, (65.8%)
ASIA B, (%)	4, (10.5%)
ASIA C, (%)	10, (26.3%)
ASIA D, (%)	11, (28.9%)
Cervical Cord, (%)	8, (21.1%)
Thoracic Cord, (%)	23, (60.5%)
Lumbar Cord, (%)	7, (18.4%)
Lesions T6 and above, (%)	18, (47.4%)
Lesions below T6, (%)	20, (52.6%)
Bladder Draining methods	
Indwelling catheters	9, (23.7%)
Suprapubic Catheter	13, (34.2%)
Intermittent self catheterization	12, (31.6%)
Voiding with control	4, (10.5%)

*At operation, SD (Standard Deviation)

Table 2 Baseline Video-urodynamic parameters.

Mean Cystometric Capacity, mls, (SD)	385.0, (173.4)
Range	130–750
Mean P_{detmax} at filling phase, cmH2O, (SD)	21.8,(14.6)
Range	10–80
Median	20
Detrusor response to filling, (%)	
Stable	17, (44.7)
Non phasic overactivity	12, (31.6%)
Phasic overactivity	5, (13.2%)
Terminal overactivity	4, (10.5%)
Vesical leak point pressure point, cmH2O, Mean, (SD)	26.1, (10.8)
Range	10–60
Median	20
Cystometric Capacity at first stress leak, mls, Mean, (SD)	173.1 (84.3)
Range	70–400
Median	130

Table 3 Additional procedures along with mid-urethral tapes.

	TVT, (%)	TOT, (%)	Mini-Slings, (%)
Nil else, (%)	11 (52.4)	5 (41.7)	1 (20)
Botulinum Toxin, (%)	8 (38.1)	2 (16.7)	3 (60)
SPC insertion + Botulium Toxin, (%)	1 (4.8%)	1 (8.3)	1 (20)
Botulinum Toxin + Macroplastique, (%)	1 (4.8%)	1 (8.3)	-
Anterior Repair	-	1 (8.3)	-
Urethral reduction + Botulinum Toxin, (%)	-	2 (16.7)	-
Total	21	12	5

Table 4 Mid-urethral tapes in spinal patients: Overall efficacy.

	TVT, (%)	TOT, (%)	Mini-Slings, (%)
N	21	12	5
Cured, (%)	11 (52.4)	6 (50.0)	3 (60.0)
Improved, (%)	2 (9.5)	3 (25.0)	1 (20.0)
Failed, (%)	8 (38.1)	3 (25.0)	1 (20.0)

difference and 10.5% reported that their life quality had deteriorated. The majority of those treated (26/38) (68.4%) stated that they would recommend this procedure to a friend with a similar problem.

Prior to tape insertion, nine patients managed their bladders with an indwelling urethral catheter, four of whom could perform clean intermittent self-catheterization (CISC) but opted for an indwelling catheter to avoid urine leakage episodes. 13 drained their bladders with a suprapubic catheter, all on free drainage due to incontinence. 12 patients performed CISC either per urethra or via a Mitrofanoff cathetirizable stoma. Four females were voiding with control but one with marked straining noted on the video-urodynamic study. 14 patients were on regular botulinum toxin injections. At the time of the mid-urethral tape procedure, three indwelling urethral catheters converted to SPC while the rest commenced CISC. Those individuals who voided with control continued to do so and those who performed CISC reduced their frequency to 4–6/24 hours.

The immediate post-operative period was uneventful for most 35/38 (92.1%). There were two cases of significant vaginal bleeds. Both patients were on high dose low molecular weight heparin (18000IU) due to previous deep vein thrombosis and pulmonary embolism. They were both managed conservatively with vaginal packs (Clavien-Dindo Grade:I). One patient returned to theatre due to a pelvic haematoma following TVT and suprapubic catheter insertion (Clavien-Dindo Grade:IIIb).

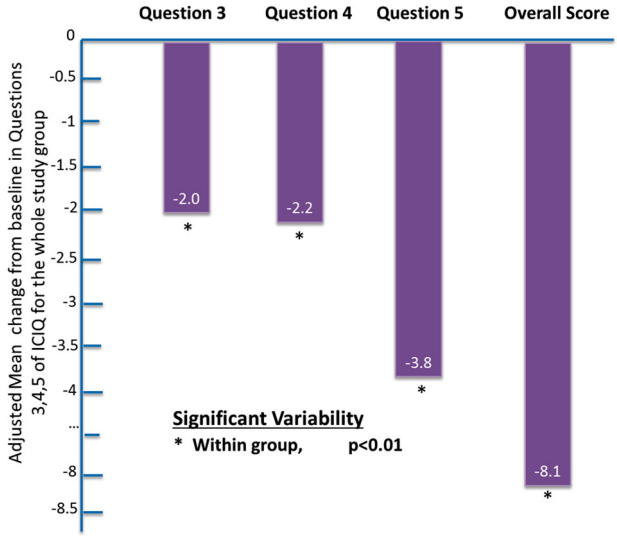


Figure 2 Overall adjusted mean change from baseline in ICIQ questions.

Nine patients (23.7%) develop tape related complications. There were five de novo urgency episodes, three after TVT and two after TOT. It is unclear whether this was due to a stimulation of proximal urethral afferent receptors or if it was due to a change in bladder behavior as a result of SCI. All were noted to have had flat traces in their pre-operative VUDS and documented detrusor overactivity postoperatively. There was a single case of vaginal extrusion following TOT necessitating tape removal at 4 months. Another patient had frequent dysreflexia episodes postoperatively and part of the tape was excised. One patient reported worsening of incontinence and increasing leakage from her SPC site. These three patients subsequently underwent clam ileocystoplasty and insertion of an artificial urinary sphincter with the cuff placed around the bladder neck.

Discussion

It would appear that spinal cord injury females with either urodynamic stress incontinence or mixed urinary incontinence have successful outcomes with mid-urethral tape surgery both in terms of continence and QoL. This study is the largest published on the efficacy of mid-urethral tapes in SCI females.

Neurogenic bladder and urinary incontinence has a significant impact on QoL in the spinal injured population.[17] It is not only that a loss of normal bladder function results in greater risk of urinary tract deterioration but also it affects their social functioning, their personal well-being and their interpersonal relationships.[18–19] Furthermore there are data to suggest that UI is related to inhibited self-care performance.[20] Bladder and bowel control and the avoidance of accidents has been demonstrated to be a priority for females with spinal injury.[21]

It may result in patients avoiding transfers in order to prevent leakage, prefer indwelling catheters, abstain from activities (including sexual intercourse) and becoming socially isolated. This negatively affects their willingness to overcome their physical disability and perform as a normal individual within the community.

Our study demonstrates that mid-urethral tapes should be included in the armamentarium of all neuro-urologist in the management of urinary incontinence in SCI female population. Our overall success was 52.6% with an additional 15.8% reporting an

Table 5 Comparison of midurethral tapes efficacy in different studies.

	Hamid *et al.*	Pannek *et al.*	Present study
N patients	12	9	38
SCI details			
Tetraplegia	0	5	8
Paraplegia	7	4	30
Cauda Equina	5	0	0
Complete Injury	3	4	13
Complete Injury	9	5	25
DO Before	1/12 (8.3%)	0	21/38 (55.3%)
DO After	1/12 (8.3%)	0	
Procedures	TVT	TOT	TVT, TOT, mini slings
Efficacy	10/12 (83.3%)	2/9 (22.2%)	
Treated	10/12 (83.3%)	2/9 (22.2%)	20/38 (52.6%)
Improved	11/12 (91.7%)	3/9 (33.3%)	26/38 (68.4%)

improvement; whilst this is lower than reported outcomes in the literature in non-neuropathic population (72.4% TVT and 78.2% TOT) it afforded our patient a minimally invasive day case procedure to correct their problem.[22] Furthermore, most patients (33/36) had weak sphincter mechanism rather than urethral hypermobility. Our group's mean vesical leak point pressure was 26.1cmH2O. Nager *et al.* proved that low vesical leak point pressure increases the risk of failure regardless of sling route.[23] A 31.5% reported that a tape didn't improve their QoL or even worsen it.

Previously published data (Table 5) have demonstrated conflicting results. Hamid *et al.* reported that TVT was an effective in treatment of SUI in SCI population, with a success rate 83.3%.[8]

However the numbers treated in this study were small with only 12 subjects' data available. Losco *et al.* reported a satisfaction rate of 85.2% after TOT insertion.[24] A similar retrospective study published by Pannek *et al.* reported a 30% success rate, again with only small numbers treated.[25]

One of the main differences in these study groups is the level of injury of the affected individuals. It can be clearly seen that the subjects included in the study by Hamid *et al.* are predominantly paraplegics. Losco *et al.* looked at levels below T12 while Pannek *et al.* looked at a mixed population including; four paraplegics and three tetraplegics. Rahman *et al.*, reported the long term follow up (median 10years) of a previously published study and they reported that seven out of nine patients were still dry.[26] Clearly there is a place for midurethral tapes in the management of SUI in SCI female population.

Our study shows a 13.2% incidence of de-novo urgency which is higher when compared to previously reported incidence in non-neuropathic patients undergoing mid-urethral tape surgery (8%) but still well within the range of the reported literature (7.2–25%).[25,27] There were 2 vaginal extrusions, which is also within the known range (2.7–33%).[25] The Clavien-Dindo IIIb complication (retropubic hematoma), it is believed to be the result of SPC insertion rather of TVT.

Interpretation of the results present here is limited because of the retrospective design of the study and the lack of postoperative urodynamic data for the whole group. In addition, more than half of patients (55.3%) received additional treatments of their lower urinary tract management. Further studies required to reach safe conclusions.

Conclusion

Mid-urethral tapes are effective in the management of SUI in SCI female patients. There are demonstrable improvements in both continence and quality of life. Clearly pre-operative assessment and careful patient selection and pre-operative counseling are required. This surgery should be offered in the setting of a dedicated spinal injuries unit after discussion in a specialist spinal/urology MDT. Furthermore the authors would recommend a full and detailed discussion with the patient of alternative treatment options available to them. The results are not as good as in non-neuropathic patients but can be acceptable after appropriate counseling.

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